Standard Operating Procedure – Participant Registration under the caBIG™ Program

This cover sheet controls the layout and components of the entire document.

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Department Approval:

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Note: This document will be issued for training on the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision. Access the caBIG™ website to verify the current revision.

Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	February 28, 2006	SOP WG Approval	All pages	Document Creation
1.0	May 9, 2006	BP SIG Approval	All pages	Document Creation
1.0	October 30, 2006	BP SIG/SOP WG	All pages	Initial release.

1. Purpose

This Standard Operating Procedure (SOP) describes the process for participant (*e.g.* patient, referring physician or principal investigator) registration during a clinical research study under the caBIG™ Program.

2. Scope

This SOP applies to the registration of participants in all clinical trial research studies sponsored by the National Cancer Institute (NCI).

3. Requirements

3.1 Prior to registering a patient in a clinical research trial, Institutional Review Board (IRB) approval must be secured for the clinical research protocol.

3.2 Patient must sign the Protocol Informed Consent form prior to performing any protocol-specified procedures.

3.3 The medical history of the patient must be verified, including evaluating eligibility requirements, prior to registering them to a protocol.

3.4 The registration accrual ceiling cannot be exceeded without authorization and/or a protocol amendment (approved by the IRB and if applicable, the sponsor) from the principal investigator or the clinical study team.

3.5 The arm-assignment information (e.g. stratification, randomization and blinding) is specified in the protocol, if applicable.

4. References/Regulations/Guidelines

Section	SOP Number	Title
4.1	N/A	Title 21CFR Part 50 Subpart B: Informed Consent of Human Subjects
4.2	N/A	ICH E6: Good Clinical Practice : Consolidated Guideline
4.3	N/A	Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule

5. Roles & Responsibilities

Role	Responsibility
Principal Investigator, or designee	• Performs all screening investigations and compares the patient characteristics with the inclusion and exclusion criteria of the protocol.
Research Nurse, or designee	• Completes patient's eligibility checklist
Study Statistician, or designee	• Performs randomization, if applicable.
Clinical Data Manager, or Central Registration Office personnel	• Enters participant information.

6. Attachments

This SOP will be used in conjunction with the following attachments. These attachments must be used by all research sites conducting clinical trials under the caBIG™ Program and can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

Title	Description
1) Procedure Description for Participant Registration	This documents the processes for registering Participants in a clinical data management application under the caBIG™ umbrella.
2) Process Flow for Participant Registration	This document identifies the workflow activities, by role, for the steps identified in the Procedure for Participant Registration.